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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,296

07/06/2006

Tadanori Mayumi

MAYUMI 4

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1444 7590 12/02/2010

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

12/02/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,296	Applicant(s) MAYUMI, TADANORI	
	Examiner Prema M. Mertz	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 8 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 8 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/2/07, 10/11/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group 13 (claims 1-4, 6, and 8-9; SEQ ID NO:21) on 10/20/2010 is acknowledged. The traversal is on the ground(s) that the restriction is improper because JP7-285997 does not disclose a tumor necrosis factor mutant protein where four or more amino acid residues selected from the group consisting of residues 29, 31, 32, 84-89, 145, 146 and 147 of SEQ ID NO:1 are replaced, the only mutant proteins disclosed in JP7-285997 are those where:

(i) the 86th amino acid residue is replaced by threonine, (2) the 86th and 29th amino acid residues are replaced by threonine and serine, respectively, (3) the 86th and 31st amino acid residues are replaced by threonine and glutamic acid, respectively, (4) the 86th and 32nd amino acid residues are replaced by threonine and tryptophan acid, respectively, (5) the 86th, 29th and 32nd amino acid residues are replaced by threonine, serine and tryptophan acid, respectively, and (6) the 86th, 31st and 32nd amino acid residues are replaced by threonine, asparagine and tryptophan acid, respectively, the mutant proteins of JP'997 only have one, two or three amino acid substitutions and cannot defeat the special technical feature shared by the presently amended claims. Applicants arguments are persuasive and all sequences set forth in SEQ ID NO:9 to 22 will be examined in the instant application.

Furthermore, with respect to the subject matter of the process claims (see In re Ochiai (37 USPQ2d 1127 (Fed. Cir. 1995)), in which a new, unobvious material is used in a known process. Ochiai determined that a process was free of the prior art if it employed a product, which was free of the prior art. However, only if the product claims are found allowable, the subject matter

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of the product claims will be rejoined with the process claims, if the process claims are of the same scope as the allowable product claims.

Claims 10-11 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-4, 6, and 8-9 are under consideration by the Examiner.

Claim rejections-35 U.S.C. 112, second paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-4, 6, 8-9, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 2, is rejected as vague and indefinite because it recites "...specific to either TNF-R1 or TNF-R2, where four or more...". This recitation is confusing for several reasons. It is unclear what TNF-R1 or TNF-R2 are and whether the mutants bind to TNF-R1 or TNF-R2. Furthermore, it is suggested that "where four or more..." be amended to recite "wherein four or more...". It is suggested that Applicants amend claim 1 to obviate this rejection.

Claim 4, line 2, is vague and indefinite because it recites "...which has an antagonistic activity". This recitation is improper because the mutant protein does not have antagonistic activity but is an antagonist of the receptor. Furthermore, it is unclear in line 5 whether the

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recitation of the residues in lines 6-7 are in addition to those recited in claim 1 or are disparate from those recited in claim 1.

Claim 9, line 1, is vague and indefinite because it recites "preparation". It is unclear if Applicants intend to claim a composition or something else.

Claims 2-3, 6 and 8 are rejected as vague and indefinite insofar as they depend on the above rejected claim 1 for their limitations.

Conclusion

Claims 1-4, 6, and 8-9 are rejected.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Prema Mertz/

Prema Mertz, Ph.D., J.D.

Primary Examiner

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